Appl. No. 09/758,832
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Attorney Docket No. MCRVT-023C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Horton, et al.
Application No. 09/758,832
Filed: January 11, 2001
For: Insitu Formable and Self-Forming Intravascular Flow Modifier (IFM) and IFM Assembly for Deployment of Same

Art Unit: 3731

Examiner: Thaler, M.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF JAY ALAN LENKER, Ph.D. PURSUANT TO 37 C.F.R. §1.132

Sir:

I, Jay Alan Lenker, do hereby declare as follows:

1. I hold bachelor's, master's and Ph.D. degrees in engineering from the Pennsylvania State University and have twenty-five (25) years of experience in the fields of biomedical engineering and medical device research and development. Specifically, I have been directly involved in research and development relating to artificial hearts & left ventricular assist devices, blood oxygenators and other cardiopulmonary bypass-related devices, prosthetic heart valves, devices and methods for treatment of benign prostatc hypertrophy and other urological disorders, stents, endovascular grafts, catheters, less invasive treatments for cerebral aneurysms and occlusive disorders, minimally invasive direct cardiac massage devices, and numerous other medical devices. I have been employed by and/or retained and a consultant to a number of medical device companies including Baxter Travenol Laboratories, Inc., Shiley, Inc., ASI, Inc., Medtronic AneuRx, Inc., MicroTherapeutics, Inc., Thera Cardia, Inc. I was also a consultant to MicroVention, Inc., the owner of the above-identified patent application, from August 1996 to August 1997, during which I gained an understanding of their developmental programs relating to the treatment f cerebrovascular aneurysms.

2. I am named as an inventor in over sixty (60) issued United States Patents and numerous pending patent applications.

2. I have been provided with, and have read, a copy of the above-identified United States Patent Application Serial No. 09/758,832 entitled "Insitu Formable and Self-Forming Intravascular Flow Modifier (IFM) and IFM Assembly for Deployment of Same" (hereinafter referred to as the "subject patent application").

3. I have also been provided with, and have read, the amended patent application claims appended hereto as Appendix A.

4. I have also been provided with, and have read, copies of the following: United States Patent No. 4,512,338 (Balko), United States Patent No. 5,122,136 (Gugliemi et al.), United States Patent no. 5,476,505 (Limon) and Massoud, Tarik F., Turjman, Francis, Ji, Cheng, Vinuela, Fernando, Gugliemi, Guido, Gobin, Y. Pierre, AND Duckwiler Gary R., *ENDOVASCULAR TREATMENT OF FUSIFORM ANEURYSMS WITH STENTS AND COILS: TECHNICAL FEASIBILITY IN A SWINE MODEL*, Am J Neuroradiol, 16:1953-1963, November 1995.

5. As of June 21, 1996, the date on which the subject patent application was filed, I do not believe that the methods recited in the amended patent application claims appended hereto as Appendix A would have been obvious to an ordinarily skilled person engaged in the design and development of catheter-based devices and methods for the treatment of cerebrovascular defects such as aneurysms, even if such person had read the Balko, Gugliemi et al. and Massoud et al. references listed in Paragraph 4 above.

6. Prior to June 21, 1996, it was common for implantable cerebrovascular occlusion coils, such as the device described in United States Patent No. 5,122,136 (Gugliemi et al.), to be attached to a portion of the delivery catheter system by way of a releasable connection that remains in tact until the operator volitionally causes the releasable connection to be severed or released. In fact, a number of currently marketed implantable cerebrovascular occlusion coils incorporate such releasable connections. The use of such releasable connections on occlusion coils is desirable because, if the occlusion coil is implanted in other than its intended location (e.g., within the lumen of a blood vessel through which blood flows), it

may result in undesirable or even catastrophic occlusion of blood flow. However, prior to June 21, 1996 it was not, to my knowledge, known for any stent or other implantable device that assumes a generally tubular shape having a hollow flow channel therethrough when implanted in the lumen of a blood vessel to incorporate such a releasable connection. In fact, the motivation to utilize a releasable connection on an occlusion coil to prevent undesirable or catastrophic accidental occlusion of a blood vessel does not generally apply to stents or other tubular implants that allow blood flow therethrough, because those stents and other tubular implants are not configured to substantially block blood flow in the manner of an occlusion coil.

7. Prior to June 21, 1996, although there are various cerebrovascular occlusion coils with releasable connections and various cerebrovascular stents without releasable connections available on the market, to the best of my knowledge, no stent having a releasable connection was then available on the market or described in the literature.

8. I believe that, if ultimately used in clinical medicine, the invention described in the subject patent application and recited in the amended claims attached hereto as Appendix B would provide a substantial advancement in the state of the art and would satisfy a long felt need in the art by providing a system for embolization of cerebrovascular aneurysms with reduced potential for migration or protrusion of the embolic member (e.g., occlusion coil) from the aneurysm and into the true lumen of the adjacent blood vessel.

I hereby declare that all statements made herein are believed to be true and all statements made on information and belief are believed to be true and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any registration resulting therefrom.

Jay Alan Lenker

Jay Alan Lenker, Ph.D.

APPENDIX A

Claim 147. A method for treating a mammalian patient who has a defect in the wall of a blood vessel that has a true lumen and a wall, said method comprising the steps of:

A. providing a system that comprises; i) a delivery catheter; ii) an intravascular member that assumes a collapsed configuration when positioned within the delivery catheter and an expanded configuration when advanced out of the delivery catheter and iii) an advancer for advancing the intravascular member out of the delivery catheter,

said intravascular member being connected to the advancer by way of a releasable connection, said releasable connection being volitionally releasable without requiring rotation of the advancer;

said intravascular member being in the form of an elongate strand when in its collapsed configuration, and

said elongate strand assuming a generally tubular shape having a hollow flow channel therethrough when the intravascular member is in its expanded configuration;

B. positioning the delivery catheter within the true lumen of the blood vessel near the defect;

C. using the advancer apparatus to advance the intravascular member out of the delivery catheter and causing the intravascular member to transition to its expanded configuration within the true lumen of the blood vessel, adjacent to the defect, such that, i) the intravascular member engages the wall of the blood vessel so as to be held in substantially fixed position within the true lumen of the blood vessel, ii) no substantial portion of the intravascular member extends into the defect and iii) blood flowing through the true lumen of the blood vessel lumen passes through the flow channel of the intravascular member; and,

D. releasing the releasable connection and removing the delivery catheter, thereby leaving the expanded intravascular member implanted within the true lumen of the blood vessel adjacent to the defect

E. providing an embolus member sized to fit within the vessel wall defect; and,

F. positioning the embolus member within the vessel wall defect such that the intravascular member retains the embolus member within the vessel wall defect.

Claim 148 A method according to Claim 147 wherein the performance of Steps B and C comprises:

placing a first catheter at a first position within the patient's vasculature;

advancing a second catheter through the lumen of the first catheter and to a second position within the patient's vasculature;

advancing the delivery catheter through the lumen of the second catheter to a third position within the true lumen of the blood vessel, adjacent to the vessel wall defect; and

while the first, second and third catheters are in their respective first, second and third positions, advancing the intravascular member out of the lumen of the third catheter such that the intravascular member assumes its expanded configuration within the true lumen of the blood vessel.

Claim 149 A method according to Claim 147 further comprising the steps of:

E. providing an embolus member sized to fit within the vessel wall defect; and,

F. positioning the embolus member within the vessel wall defect such that the intravascular member retains the embolus member within the vessel wall defect.

Claim 150 A method according to Claim ~~149~~ 147 wherein Step F is performed after Step C.

Claim 151 A method according to Claim ~~149~~ 147 wherein Step F is performed before Step C.

Claim 152 A method according to Claim ~~149~~ 147 wherein Step F comprises:

i positioning a delivery catheter having a distal end within the intravascular member after completion of Step C;

ii causing the distal end of the delivery catheter to advance through a portion of the intravascular member and into the vessel wall defect;

iii delivering the embolus member out of the distal end of the delivery catheter and into the vessel wall defect; and,

iv removing the delivery catheter, leaving the embolus member within the vessel wall defect with the intravascular member preventing the embolus member from escaping from the vessel wall defect into the lumen of the blood vessel.

Claim 153 A method according to Claim 147 wherein the vessel wall defect is an aneurysm and wherein Step F comprises positioning the embolus member within the interior of the aneurysm and outside of the true lumen of the blood vessel.

Claim 154 A method according to Claim 147 wherein the aneurysm is a wide mouthed aneurysm and wherein Step F comprises delivering the embolus member through the mouth of the aneurysm and into the aneurysm sac.

Claim 155 A method according to Claim 147 wherein at least a portion of the embolic member delivered in Step F is thrombogenic.

Claim 156 A system for treating an aneurysm or other defect in the wall of a blood vessel that has a wall and a true lumen through which blood normally flows, said system comprising:

an elongate, flexible delivery catheter having a lumen extending longitudinally therethrough and a distal end opening, said delivery catheter being advanceable in to the true lumen of a blood vessel;

an intravascular member that has a collapsed configuration wherein it is in the form of an elongate strand member that is positionable within the delivery catheter and an expanded configuration wherein ~~it is~~ the elongate strand member assumes a generally tubular shape that defines a hollow flow channel therethrough;

an advancer for advancing the intravascular member out of the delivery catheter, said intravascular member being connected to the advancer by way of a releasable connection, said releasable connection being volitionally releasable without requiring rotation of the advancer; and

an embolic member that is implantable within the aneurysm or other defect in the wall of the blood vessel;

said advancer being useable to advance the intravascular member out of the distal end opening of the delivery catheter such that the intravascular member expands to its expanded configuration within the true lumen of the blood vessel in an orientation that is substantially coaxial with the advancer and such that blood flowing through the blood vessel lumen will flow through the flow channel of the intravascular member, while the intravascular member remains connected to the advancer apparatus by way of said releasable connection;

said releasable connection being thereafter volitionally severable such that the delivery catheter and advancer apparatus my be removed from the blood vessel lumen leaving the expanded intravascular member implanted in said blood vessel lumen

said embolic member being implantable within the aneurysm or other defect such that the intravascular member prevents the embolic member from escaping from the aneurysm or other defect and into the true lumen of the blood vessel.

Claim 157 (Cancelled)

Claim 158 A system according to Claim ~~157~~ wherein the elongate strand member forms [[a]] at least one helix when in said expanded configuration.

Claim 159 A system according to Claim 156 further comprising apparatus for releasing the releasable connection.

Claim 160 A system according to Claim 156 wherein the releasable connection comprises a ball and claw.

Claim 161 A system according to Claim 156 wherein the releasable connection is releasable by being cut and wherein the apparatus for releasing the releasable connection comprises apparatus for cutting the releasable connection.

Claim 162 (Previously Added) A system according to Claim 156 wherein the releasable connection is releasable in response to an electrical current and wherein the apparatus for releasing the releasable connection comprises apparatus for delivering electrical current.